III. REMARKS

The undersigned gratefully acknowledges the Examiner's indication in the last Office Action that claim 25 would be allowable if rewritten in dependent form, which has been done by virtue of this amendment, without prejudice to applicants pursuing remaining subject matter in continuation applications. It is respectfully submitted that this amendment places the previously deemed allowable subject matter into condition for allowance.

A. Status of the Claims

The Examiner indicated that Claim 25 would be allowable if rewritten in independent from including all of the limitations of the base claim and any intervening claims. Therefore, Claim 1 has been amended to incorporate Claim 25. It is respectfully submitted that no new matter has been added by virtue of this amendment.

Claims 1, 4-5, 7-11, 14-15, 26-31 and 35-37 are pending. Claims 12-13, 19-21, and 23-25 have been cancelled without prejudice by virtue of this amendment. Claims 1 and 18 have been amended without prejudice by virtue of this amendment. The Examiner indicated that Claim 25 would be allowable if rewritten in independent from including all of the limitations of the base claim and any intervening claims. Therefore, Claim 1 has been amended to incorporate Claim 25. It is respectfully submitted that no new matter has been added by virtue of this amendment.

New claims 35 – 37 have been added which are directed to particular dosage strengths to be administered via the method set forth in amended claim 1. Support for these different strengths is found throughout the specification, including page 7 lines 19 – 26; page 8, lines 3-9. Original claims as filed and as pending specifically call for dosage strengths of 1000 and 2000 mg metformin, among other strengths. In this regard, the Examiner is reminded that, as stated in the specification at page 7, lines 4 – 10, "a given plasma level (e.g., C_{max}) of metformin per

specified dose will be directly proportional to other doeses of metformin. Such proportional doses and plasma levels are contemplated to be within the scope of the invention and to be within the scope of the appended claims." Applicants point out that the previous amendment to claims 22 -25 was intended to clarify that the particular ranges of the claimed pharmacokinetic parameters (i.e., C_{max} and AUC) were directed to the 2000 mg dose, and were not intended to limit the scope of the claims solely to a 2000 mg dosage strength.

B. Claim objection

In the Office Action, claim 18 was objected to as depending from cancelled claim 17. Claim 18 has been amended to depend from claim 1. The Examiner is requested to withdrawal this objection.

C. Rejection of Claim 18 under 35 U.S.C. §112, second paragraph

In the Office Action, claim 18 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The Examiner notes that claim 18 depends from cancelled claim 17.

In response, claim 18 has been amended to depend from claim 1. Therefore, the Examiner is requested to withdrawal this rejection.

D. Rejections of Claims 1, 4-5, 7-15, 18-24, and 26-31 under 35 U.S.C. 103(a) over Lewis et al. in combination with Chiao and Drug Facts and Comparisons OR Moeckel et al. in combination with Chiao and Drug Facts and Comparisons

Claims 1, 4-5, 7-15, 18-24, 26-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (WO 00/28989; hereafter '989) in combination with Chiao (Remington, 1995) and further in combination with Drug Facts and Comparisons (1999) OR Moeckel et al (5,955,106; hereafter '106) in combination with Chiao (Remington, 1995) and further in combination with Drug Facts and Comparisons (1999)."

The Examiner states that "it would have been obvious to one skilled in the art at the time of the invention to combine '989 with Chaio and DFC or '106 with Chiao and DFC with the motivation of providing controlled delivery of metformin over a desired period of time to lower blood glucose levels when an individual is in the fed state. Applicant's comments filed 3-4-03, Paper #11, stating that numerous controlled release technologies are well within the knowledge of pharmaceutical formulators having ordinary skill in the art and such pharmaceutical formulators know that controlled release can be manipulated, e.g., by varying the amount of controlled release carrier (among other things), to provide a formulation which upon *in vivo* testing will provide the Tmax range of the present invention (pages 8-9 of response), are also relied upon for supporting the above position.

In view of the amendment to claim 1, incorporating allowable claim 25 of the present application, the Examiner's rejection with respect to Claims 1, 4-5, 7-15, 18-24, and 26-31 under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (WO 00/28989; hereafter '989) in combination with Chiao (Remington, 1995) and further in combination with Drug Facts and Comparisons (1999) OR Moeckel et al (5,955,106; hereafter '106) in combination with Chiao (Remington, 1995) and further in combination with Drug Facts and Comparisons (1999) is now moot. The Examiner is respectfully requested to remove this rejection.

E. Rejections of Claims 1, 4-5, 7-15, 18-24, and 26-31 under 35 U.S.C. 103(a) over Cheng et al. in view of Drug Facts and Comparisons

Claims 1, 4-5, 7-15, 18-24, and 26-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (WO 99/47125; hereafter '125) in view of Drug Facts and Comparisons (1999).

The Examiner states that "it would have been obvious to one skilled in the art at the time of the invention to manipulate the release profile of '125 in accordance with the teachings in '770 and lower blood glucose levels accordingly with the motivation of providing controlled

delivery of metformin over a desired period of time and to administer the compositions at dinner or at a fed state with the motivation of regulating sugar levels.

In view of the present amendment, claims 32-34 of the present application have been canceled without prejudice rendering the Examiner's rejection moot. Therefore, the Examiner is respectfully requested to withdraw the rejection of claims 32-34 under 35 U.S.C. §102(b) for the above-referenced application.

In view of the amendment to claim 1, incorporating allowable claim 25 of the present application, the Examiner's rejection with respect to Claims 1, 4-5, 7-15, 18-24, and 26-31 under 35 U.S.C. 103(a) as being unpatentable over Cheng et al (WO 99/47125; hereafter '125) in view of Drug Facts and Comparisons (1999) is now moot. The Examiner is respectfully requested to remove this rejection.

F. Double Patenting Rejections

Claims 1, 4-5, 7-15, and 18-31 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the following:

claims 1-29 of U.S. Patent No. 6,099,859;

claims 1-39 of U.S. Patent No. 6,284,275; and

claims 1-4 of U.S. Patent No. of U.S. Patent no. 6,099,862.

In addition claims 1, 4-5, 7-15, and 18-31 were provisionally rejected over claims 1-29 of copending Application No. 09/726,193.

In response, Applicants will consider the filing of Terminal Disclaimers to obviate the double-patenting rejections upon indication from the Examiner that the claims are otherwise allowable.

G. Conclusion

It is now believed that the above-referenced rejections and objections have been obviated and it is respectfully requested that the rejections and objections be withdrawn. It is believed that all claims are now in condition for allowance.

According to currently recommended Patent Office policy the Examiner is specifically authorized to contact the undersigned in the event that a telephonic interview will advance the prosecution of this application.

An early and favorable action is earnestly solicited.

Respectfully submitted,
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